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600 CONGRESS AVENUE, SUITE 2400
AUSTIN, TEXAS 78701-3271
WWW.FULBRIGHT.COM

DAVID L. PARKER
PARTNER
DPARKER@FULBRIGHT.COM

DIRECT DIAL: (512) 536-3055
TELEPHONE: (512) 474-5201
FACSIMILE: (512) 536-4598

February 18, 2005

CERTIFICATE OF MAILING 37 C.F.R. 1.8

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February 18, 2005

Date

David L. Parker

MS AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

RE: *U.S. Patent Application No. 10/801,277 entitled "METHODS OF TREATING AUTOIMMUNE DISEASES USING TYPE ONE INTERFERONS" – Staley A. Brod*

Our reference: CLFR:115USC1

Client reference: D5716CIP4/C

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and references A1-A7, B1-B3, C1-C3, C6-C13, C16-C18, C21, C23-C25, C27-C30, C32-C37, C40-C46, and C49.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/CLFR:115USC1.

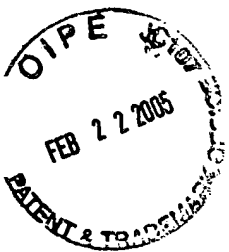
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Respectfully submitted,

David L. Parker
Reg. No. 32,165

DLP/kvp

Encl.: as noted



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Staley A. Brod

Serial No.: 10/801,277

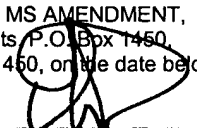
Filed: March 16, 2004

For: METHODS OF TREATING
AUTOIMMUNE DISEASES USING TYPE
ONE INTERFERONS

Group Art Unit: 1761

Examiner: Unknown

Atty. Dkt. No.: CLFR:115USC1

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February 18, 2005	
Date	David L. Parker

INFORMATION DISCLOSURE STATEMENT

MS AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

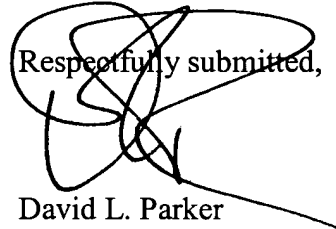
In accordance with 37 C.F.R §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/CLFR:115USC1.

This application is a continuation-in-part application of Serial No. 08/946,710, filed October 8, 1997 which is a continuation-in-part application of Serial No. 08/631,470, filed April 12, 1996 which is a continuation-in-part application of Serial No. 08/408,271, filed March 24, 1995 which is a continuation-in-part application of Serial No. 08/226,631, filed April 12, 1994 and is relied upon for an earlier filing date under 35 U.S.C. § 120. In accordance with Rule 37 C.F.R. § 1.98(d) only copies of those documents not previously cited and submitted to the Patent and Trademark Office in the above referenced prior application Serial Numbers are enclosed for the convenience of the Examiner.

Applicant respectfully requests that the listed documents be made of record in the present case.

Respectfully submitted,


David L. Parker
Reg. No. 32,165
Attorney for Applicant

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 474-5201

Date: February 18, 2005

Form PTO-1449 (modified)

Atty. Docket No.

CLFR:115USC1

Serial No.

10/801,277

List of Patents and Publications for Applicant's

Applicant

Staley A. Brod

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Filing Date:

March 16, 2004

Group:

1761

U.S. Patent Documents

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Foreign Patent Documents

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Other Art

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U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	4,409,243	10/11/83	Lieb	424	330	11/9/81
	A2	4,462,985	7/31/84	Cummins	424	85	9/7/82
	A3	4,497,795	2/5/85	Cummins	424	85.6	12/13/82
	A4	5,019,382	5/28/91	Cummins	424	85.4	1/17/90
	A5	5,093,338	3/3/92	Byrne	514	291	4/23/91
	A6	5,624,895	4/29/97	Sobel	514	8	2/18/94
	A7	5,780,021	7/14/98	Sobel	424	85.4	3/5/93

Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 94/20122	9/15/94	WIPO			English
	B2	WO 96/28183	9/19/96	WIPO			English
	B3	WO 83/03411	10/13/83	WIPO			English

Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	"Interferon beta-1b is effective in relapsing-remitting multiple sclerosis. I. Clinical results of a multicenter, randomized, double-blind, placebo-controlled trial. The IFNB Multiple Sclerosis Study Group," <i>Neurology</i> 43:655-661. 1993.
	C2	Bayley <i>et al.</i> , "The transmucosal absorption of recombinant human interferon-alpha B/D hybrid in the rat and rabbit," <i>J. Pharm. Pharmacol.</i> 47(9):721-724. 1995.
	C3	Bocci <i>et al.</i> , "Is interferon effective after oral administration? The state of the art." <i>J. Biol. Regul. Homeos. Agents</i> , 4(2):81-83, 1990.
	C4	Bocci, "Absorption of cytokines via oropharyngeal-associated lymphoid tissues," <i>Clin Pharmacokinet</i> , 21(6):411-417, 1991.

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Form PTO-1449 (modified)		Atty. Docket No. CLFR:115USC1	Serial No. 10/801,277
List of Patents and Publications for Applicant's INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant Staley A. Brod	
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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C5	Bocci, "Immunomodulators as local hormones: new insights regarding their clinical utilization," <i>Journal of Biological Response Modifiers</i> , 4:340-352, 1985.
	C6	Bosio <i>et al.</i> , "Efficacy of low-dose oral use of type I interferon in cytomegalovirus infections in vivo," <i>J. Interferon Cytokine Res.</i> , 19:869-876, 1999.
	C7	Brod and Khan "Oral administration of IFN- α is superior to subcutaneous administration of IFN- α in the suppression of chronic relapsing experimental autoimmune encephalomyelitis," <i>J. Autoimmunity</i> , 9:11-20, 1996.
	C8	Brod <i>et al.</i> , "Ingested (oral) IFN-alpha induces MxA mRNA in RRMS" (Submitted for publication)
	C9	Brod <i>et al.</i> , "Ingested IFN- α has biological effects in humans with relapsing-remitting multiple sclerosis," <i>Mult. Scler.</i> , 3:1-7, 1997.
	C10	Brod <i>et al.</i> , "Ingested interferon α suppresses type I diabetes in non-obese diabetic mice," <i>Diabetologia</i> , 41:1227-1232, 1998.
	C11	Brod <i>et al.</i> , "Ingested interferon alpha induces Mx mRNA," <i>Cytokine</i> , 11:1-8, 1999.
	C12	Brod <i>et al.</i> , "Ingested interferon alpha preserves residual beta cell function type 1 diabetes," <i>J. Interferon Cytokine Res.</i> , 2(12):1021-1030, 2001.
	C13	Brod, "Hypothesis: multiple sclerosis is a type I interferon deficiency syndrome," <i>Proc. Soc. Exp. Biol. Med.</i> 218:278-283, 1998.
	C14	Butcher, "The regulation of lymphocyte traffic," <i>Current Topics in Microbiology and Immunology</i> , 128:85-122, 1986.
	C15	Cantell and Pyhala, "Circulating interferon in rabbits after administration of human interferon by different routes," <i>Virology</i> , 20:97-104, 1973.
	C16	Carter <i>et al.</i> , "Disease modifying therapies in multiple sclerosis," <i>CNS Drugs</i> , 3:99-114, 1995.
	C17	Connelly, "Interferon beta for multiple sclerosis," <i>Ann. Pharmacother.</i> , 28(5):610-616, 1994.
	C18	Dhingra <i>et al.</i> , "A phase-I clinical study of low-dose oral interferon-alpha," <i>J. Immunother.</i> , 14(1):51-55, 1993.
	C19	Fleischmann <i>et al.</i> , "Orally administered interferons exert their white blood cell suppressive effects via a novel mechanism," <i>Neurology</i> , 13, 1993.

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	C20	Gibson <i>et al.</i> , "Pharmacokinetics of recombinant leukocyte A interferon following various routes and modes of administration to the dog," <i>Journal of Interferon Research</i> , 5:403-408, 1985.
	C21	Giron <i>et al.</i> , "Effect of interferons and poly(I):poly(C) on the pathogenesis of the diabetogenic variant of encephalomyocarditis virus in different mouse strains," <i>J. Interferon Res.</i> , 8(6):745-753, 1988.
	C22	Goldsteain <i>et al.</i> , "Human biologic response modification by interferon in the absence of measurable serum concentrations: a comparative trial of subcutaneous and intravenous interferon- β serine," <i>Journal of the National Cancer Institute</i> , 81(14):1061-1068, 1989.
	C23	Goodkin <i>et al.</i> , "Experimental therapies for multiple sclerosis: current status," <i>Cleve. Clin. J. Med.</i> , 59:63-74, 1992.
	C24	Gross <i>et al.</i> , "Interferon- α with condylomata acuminata and juvenile diabetes mellitus," <i>Deutsche Medizinische Wochenschrift</i> , 111(36):1351-1355, 1986. (Abstract)
	C25	Higgins <i>et al.</i> , "Suppression of experimental autoimmune encephalomyelitis by oral administration of myelin basic protein and its fragments," <i>J. Immunol.</i> 140:440-445, 1988.
	C26	Horisberger, "MX protein: function and mechanism of action, <i>Biotechnology</i> , Ciba-Geigy Ltd., CH-4002 Basel, Switzerland.
	C27	Hutchison <i>et al.</i> , "Chronic recurrent aphthous stomatitis: oral treatment with low-dose interferon alpha," <i>Mol. Biother.</i> , 2:160-164, 1990.
	C28	Koech <i>et al.</i> , "Efficacy of Kemron (low dose oral natural human interferon alpha) in the management of HIV-1 infection and acquired immune deficiency syndrome (AIDS)," <i>East Afr. Med. J.</i> , 67(7 Supp 2):SS64-70, 1990.
	C29	Koech <i>et al.</i> , "Low dose oral alpha-interferon therapy for patients seropositive for human immunodeficiency virus type-1 (HIV-1)," <i>Mol. Biother.</i> , 2(2):91-95, 1990.
	C30	Konrad <i>et al.</i> , <i>Biological Barriers to Protein Delivery</i> , ch. 14, 409-437, ed. Audus et al. 1993.
	C31	Larocca <i>et al.</i> , "Evaluation of neutralizing antibodies in patients treated with recombinant interferon- β ser," <i>Journal of Interferon Research</i> , 9(Supp 1):S51-S60, 1989.
	C32	Lecce <i>et al.</i> , "Treatment of rotavirus infection in neonate and weanling pigs using natural human interferon alpha," <i>Mol. Biother.</i> 2(4):211-216, 1990.

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Exam. Init.	Ref. Des.	Citation
	C33	Liu <i>et al.</i> , "Accumulation of protein O-GlcNAc modification inhibits proteasomes in the brain and coincides with neuronal apoptosis in brain areas with high O-GlcNAc metabolism," <i>J. Neurochem.</i> , 89(4):1044-1055.
	C34	Mashkovskii <i>et al.</i> , "Drugs," Moscow, Meditsina, 2:389-392, 1993.
	C35	Mowat <i>et al.</i> , "The regulation of immune responses to dietary protein antigens," <i>Immun. Today</i> , 8:93-98, 1987.
	C36	Nagler <i>et al.</i> , "Immunotherapy with recombinant human interleukin-2 and recombinant interferon-alpha in lymphoma patients postautologous marrow or stem cell transplant," <i>Blood</i> , 89:3951-5959.
	C37	Owens <i>et al.</i> , "The immunology of multiple sclerosis and its animal model, experimental allergic encephalomyelitis," <i>Neurol. Clin.</i> , 13(1):51-73, 1995.
	C38	Paulesu <i>et al.</i> , "Oral administration of human recombinant interferon-a2 in rats," Elsevier Science Publishers B.V. (Biomedical Division), 46:199-202, 1988.
	C39	Radwanski <i>et al.</i> , "Pharmacokinetics of interferon α -2b in healthy volunteers," <i>J Clin Pharmacol</i> , 27:432-435, 1987.
	C40	Satoh <i>et al.</i> , "Suppression of late asthmatic response by low-dose oral administration of interferon-beta in the guinea pig model of asthma," <i>J. Interferon Cytokine Res.</i> , 19:887-894, 1999.
	C41	Schafer <i>et al.</i> , "Interferon administered orally: protection of neonatal mice from lethal virus challenge," <i>Science</i> , 176:1326-1327, 1972.
	C42	Shibutani <i>et al.</i> , "Toxicity studies of human fibroblast interferon beta (I) acute and subacute toxicity studies in mice and rats," <i>Iyakuin Kenkyu</i> , 18:571-582. (1987) (Abstract)
	C43	Shim <i>et al.</i> , "Administration route dependent bioavailability of interferon- α and effect of bile salts on the nasal absorption," <i>Drug Dev. Indus. Pharm.</i> , 19:1183-1199. 1993.
	C44	Thompson <i>et al.</i> , "Gastric administration of type II collagen delays the onset and severity of collagen-induced arthritis in rats," <i>Clin. Exp. Immunol.</i> , 64(3):581-586, 1985.
	C45	Vial <i>et al.</i> , "Clinical toxicity of the interferons," <i>Drug Saf.</i> , 10(2):115-150, 1994.
	C46	Wedner <i>et al.</i> , <i>Basic Clinical Immunology</i> , 7 th edition Chap 34, 1991

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Exam. Init.	Ref. Des.	Citation
	C47	Wills <i>et al.</i> , "Pharmacokinetics of recombinant alpha A interferon following IV infusion and bolus, IM, and PO administration to African green monkeys," <i>Journal of Interferon Research</i> , 4(3):399-409, 1984.
	C48	Witt <i>et al.</i> , "Absence of biological effects of orally administered interferon- β ser," <i>Journal of Interferon Research</i> , 12:411-413, 1992.
	C49	Yershov <i>et al.</i> , "Interferon status in different diseases," <i>Voprosy Virusologii</i> , 35:444-448, 1990 (Russian)

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